

Approval Date: _____

FREEDOM OF INFORMATION SUMMARY

PROGRAM[®] (lufenuron) FLAVOR TABS[®]

Supplemental NADA 141- 035

Novartis Animal Health US, Inc.

Greensboro, NC 27408

This supplemental New Animal Drug Application is for the concurrent use of PROGRAM[®] Flavor Tabs[®] and CAPSTAR[®] Tablets to kill adult fleas and prevent flea eggs from hatching. The effects of PROGRAM[®] Flavor Tabs[®], which prevent and control flea populations, and CAPSTAR[®] Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM[™].

NADA 141-035

NFR

100

100-100-100

1. GENERAL INFORMATION:

- a. File Number: NADA 141-035
- b. Sponsor: Novartis Animal Health US, Inc.
3200 Northline Ave. Suite 300
Greensboro, NC 27408
Drug Labeler Code: 058198
- c. Established Name: Lufenuron
- d. Proprietary Name: PROGRAM[®] Flavor Tabs[®]
- e. Dosage Form: Oral tablet
- f. How Supplied: PROGRAM[®] Flavor Tabs[®] are available in four tablet sizes (see Dosage section), formulated according to the weight of the dog and cat. Each tablet size is available in color-coded packages containing six tablets.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Refer to the dosage section.
- i. Route of Administration: Oral
- j. Species/Class: Dogs and Cats
- k. Recommended Dosage:

For Use in Dogs: PROGRAM[®] Flavor Tabs[®] are given orally, once a month, at the recommended minimum dosage of 4.5 mg/lb (10 mg/kg).

Recommended Dosage Schedule for Dogs	
Body Weight	Lufenuron Per Tablet
Up to 10 lbs	45 mg
11-20 lbs	90 mg
21-45 lbs	204.9 mg
46-90 lbs	409.8 mg

Dogs over 90 lbs are provided the appropriate combination of tablets.

For Use in Cats: PROGRAM[®] Flavor Tabs[®] are given orally, once a month, at the recommended minimum dosage of 13.6 mg/lb (30 mg/kg).

Recommended Dosage Schedule for Cats

Body Weight	Lufenuron Per Tablet
Up to 6 lbs	90 mg
7 - 15 lbs	204.9 mg

Cats over 15 lbs are provided the appropriate combination of tablets.

The dosage schedule for the concurrent use of CAPSTAR[®] Tablets and PROGRAM[®] Flavor Tabs[®] is addressed in NADA 141-205.

- l. Pharmacological Category: Lufenuron is an insect development inhibitor.
- m. Indications: PROGRAM[®] Flavor Tabs[®] are indicated for use in dogs and puppies four weeks of age and older for the prevention and control of flea populations and in cats and kittens, four weeks of age and older for the control of flea populations.
- n. Effect of Supplement: Approval of this supplemental NADA will change the labeling for NADA 141-035.
1. The minimum age for dosing is changed from 6 weeks to 4 weeks.
 2. There are some minor revisions to clarify the currently approved text in the package insert.
 3. The package insert is revised to include reference to the concurrent use of CAPSTAR[®] (nitenpyram) Tablets (NADA 141-175) to kill adult fleas. The information supporting approval for this concurrent use is documented in NADA 141-205.

4. The unit dose cartons are revised to refer to concurrent use with CAPSTAR[®] Tablets.
5. Each unit dose carton will contain an additional "FLEA MANAGEMENT SYSTEM[™]" package insert that provides specific information for using CAPSTAR[®] Tablets with PROGRAM[®] Flavor Tabs[®].

2. EFFECTIVENESS:

- a. For information about the effectiveness of PROGRAM[®] Flavor Tabs[®] please refer to the FOI summary for the original PROGRAM[®] approval dated November 23, 1994 (E-0001) and the supplemental FOI Summary dated January 23, 1997 (C-0024).
- b. For information about the effectiveness of the concurrent use of CAPSTAR[®] Tablets with PROGRAM[®] Flavor Tabs[®] please refer to the FOI summary for NADA 141-205 (A-0000).

3. TARGET ANIMAL SAFETY:

- a. For information about the safety of PROGRAM[®] Flavor Tabs[®] please refer to the FOI summary for the original PROGRAM[®] approval dated November 23, 1994 (E-0001) and the supplemental FOI Summary dated January 23, 1997 (C-0024). The decision to change the minimum age for use from 6 weeks to 4 weeks is based on re-evaluation of data submitted for the original approval.
- b. For information about the safety of PROGRAM[®] Flavor Tabs[®] used concurrently with CAPSTAR[®] Tablets please refer to the FOI summary for NADA 141-205 (A-0000).

4. HUMAN SAFETY:

This drug is intended for use in dogs and cats which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children."

5. AGENCY CONCLUSIONS:

The data in support of this NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that PROGRAM[®] Flavor Tabs[®] when used in accordance with the directions provided by the revised labeling, are safe and effective for the prevention and control of flea populations.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the concurrent use with CAPSTAR[®] Tablets (nitenpyram) for which this supplement is approved.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

PROGRAM[®] Flavor Tabs[®] are under the following U.S. patent numbers:
Patent 5,416,102 expires May 30, 2012; Patent 5,420,163 expires May 30, 2012;
Patent 5,153,224 expires October 6, 2009; Patent 4,798,837 expires January 31, 2006.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below.

- a. Package Inserts—canine (front), feline (back)
- b. Unit Dose Cartons - 45 mg, 90 mg, 204.9 mg, 409.8 mg



Information for Dosing Dogs

The flavored once-a-month tablet that prevents and controls flea populations in dogs.

Introduction

Novartis Animal Health encourages you to take the time to read this package insert which describes the use of PROGRAM® (lufenuron) Flavor Tabs® as a convenient monthly flea control treatment. Controlling flea infestations is very important to the health of your pet.

After reading this insert if you have any questions about PROGRAM Flavor Tabs, flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's healthcare expert.

Warnings

Not for human use. Keep this and all drugs out of the reach of children.

Administration

TO ENSURE ADEQUATE ABSORPTION, ALWAYS ADMINISTER PROGRAM FLAVOR TABS TO DOGS IMMEDIATELY AFTER OR IN CONJUNCTION WITH A NORMAL MEAL.

Be certain the dog consumes the entire tablet or tablets. As an alternative to direct dosing, tablets may be offered in food. Watch the dog closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

Treatment with PROGRAM Flavor Tabs may begin at any time of year. In geographic areas where flea infestations are seasonal, the treatment schedule should begin several weeks prior to the expected onset of infestations. Treatments should continue until the end of "flea season." If there is risk of exposure to fleas year-round, then treatment should continue the entire year without interruption. Ask your veterinarian for details concerning your geographic area and the most effective treatment schedule for your pet.

Description

The active ingredient of PROGRAM Flavor Tabs is lufenuron, a benzoylphenylurea derivative classified as an insect development inhibitor (IDI).

As an insect development inhibitor, PROGRAM Flavor Tabs do not kill adult fleas but effectively and safely control flea populations on your pet by breaking the flea's life cycle at the egg stage.

Indications

PROGRAM Flavor Tabs are labeled for use in dogs and puppies, four weeks of age and older, for the prevention and control of flea populations.

Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. You may also need to use a product that kills adult fleas.

PROGRAM Flavor Tabs may be used along with CAPSTAR (nitenpyram) Tablets to provide a Flea Management System that kills adult fleas and prevents flea eggs from hatching. Please see the Supplemental Package Insert provided with this product for information about using the two products together.

Without concurrent use of an adulticide, adequate flea control may not be achieved in dogs that have repeated exposure to flea infested animals or environments.

Precautions

PROGRAM Flavor Tabs have no effect on adult fleas but act to immediately break the flea life cycle by preventing eggs from developing into adults. However, pre-existing immature fleas in the dog's environment may continue to develop and emerge as adults after treatment with PROGRAM Flavor Tabs has begun. Based on results of clinical studies, this emergence generally occurs during the first 30-60 days. Therefore, if your pet already has a flea infestation before starting PROGRAM Flavor Tabs, noticeable results may not be observed until several weeks after dosing. In cooler climates, immature fleas may take longer to complete the life cycle and emerge as adults.

To speed control, products that kill adult fleas, like Capstar may be used temporarily with PROGRAM Flavor Tabs, depending on the severity of the infestation. Your veterinarian can recommend the most effective treatment plan for your pet.

To ensure that your pet gets the greatest benefit from PROGRAM Flavor Tabs, you must administer the tablet or tablets once a month in conjunction with a normal meal. If you miss the 30-day interval, give PROGRAM Flavor Tabs immediately and resume your monthly dosing schedule. It is important to treat all dogs in the household. Fleas can reproduce on untreated pets and allow infestations to persist. All cats in the household should be treated with an approved product like lufenuron.

The active ingredient in Program Flavor Tabs is excreted in high concentrations in the milk,

however, no resulting adverse effects have been recognized.

Flea Infestations on Dogs

Although other flea species may be found on dogs, the cat flea (*Ctenocephalides felis*) is the predominant flea associated with infestations on dogs in the United States. In addition to the common nuisance irritations associated with infestations, fleas can be responsible for medical problems in your pet such as flea allergy dermatitis (FAD), a skin reaction to flea bites. Fleas also transmit other parasites, including tapeworms. Controlling flea infestations is important to your pet's health while also reducing the major and minor annoyances associated with these parasites.

The following diagram illustrates the flea's life cycle and where PROGRAM Flavor Tabs acts to break this cycle.

Life Cycle of the Flea



Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can

develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your dog and subsequently lay eggs that drop off your dog's coat. Within days, larvae hatch from the eggs and live undetected in your dog's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and when appropriately stimulated, a young adult flea emerges and jumps onto your dog to continue the life cycle. After biting a PROGRAM Flavor Tabs treated dog, the female flea ingests lufenuron which is deposited in her eggs. Lufenuron prevents these flea eggs from developing into mature adults. This safe and convenient approach to flea control effectively breaks the flea's life cycle and controls flea populations.

Dosage

PROGRAM Flavor Tabs are given orally, once a month, at the recommended minimum dosage of 4.5 mg lufenuron per pound (10 mg/kg) of body weight.

Prog w/ capstar K9 DRAFT
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Recommended Dosage Schedule

Body Weight	Dose	Lufenuron Per Tablet
Up to 10 lbs.	One tablet	45.0 mg
11 to 20 lbs.	One tablet	90.0 mg
21 to 45 lbs.	One tablet	204.9 mg
46 to 90 lbs.	One tablet	409.8 mg

Dogs over 90 lbs. should receive the appropriate combination of tablets.

***Please see supplemental insert in this package for concurrent dosing of PROGRAM Flavor Tabs and CAPSTAR Tablets.**

Once-A-Month

PROGRAM Flavor Tabs will safely and effectively control flea infestations only if administered in conjunction with a normal meal on a monthly dosing schedule. To help you remember the monthly dosing, use the enclosed reminder stickers on the appropriate dates on your calendar.

Adverse Reactions

The following adverse reactions have been reported in dogs after giving PROGRAM Flavor Tabs: vomiting, depression/ lethargy, pruritus (itchy, scratchy skin), urticaria (wheals, hives), diarrhea, anorexia (loss of appetite), and skin congestion (red skin).

How Supplied

PROGRAM Flavor Tabs are available in four tablet sizes (see Dosage section), formulated according to the weight of the dog. Each tablet size is available in color-coded packages of six tablets each.

Storage Conditions

PROGRAM Flavor Tabs should be stored at room temperature between 59° and 86°F (15-30°C).

Questions? Comments?
Please call 1-800-332-2761
Visit our website at www.petwellness.com

Manufactured for: Novartis Animal Health US, Inc.
Greensboro, NC 27408, USA

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NADA # 141-035, Approved by FDA

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NAH/PRO-Ft/PI/3
Draft 01/03

PROGRAM[®]

(LUFENURON) Flavor Tabs[®]

Information for Dosing Cats

The once-a-month flavored tablet that controls flea populations on cats.

Introduction

Novartis Animal Health encourages you to take the time to read this package insert which describes the use of PROGRAM[®] (lufenuron) Flavor Tabs[®] as a convenient monthly flea control treatment. Controlling flea infestations is very important to the health of your cat. After reading this insert, if you have any questions about PROGRAM Flavor Tabs, flea control, or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.

Warnings

Not for human use. Keep this and all drugs out of the reach of children.

Administration

TO ENSURE ADEQUATE ABSORPTION, ALWAYS ADMINISTER PROGRAM FLAVOR TABS IN CONJUNCTION WITH A NORMAL MEAL.

Be certain the cat consumes the entire tablet or tablets. The tablets can be broken prior to direct dosing for ease of administration to small cats and kittens. As an alternative to direct dosing, the tablets can be broken and mixed into wet food. In multiple cat households, each cat should be treated separately to achieve adequate dosing. Watch the cat closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

Treatment with PROGRAM Flavor Tabs may begin at any time of year. Treatment should continue until the end of "flea season." If there is a risk of exposure to fleas year-round, then treatment should continue the entire year without interruption. Ask your veterinarian for details concerning your geographic area and the most effective treatment schedule for your cat.

Description

PROGRAM Flavor Tabs are available in two sizes of tablets for oral administration to cats and kittens according to their weight (see Dosage section). The active ingredient of PROGRAM Flavor Tabs is lufenuron, a benzoylphenyl-urea derivative classified as an insect development inhibitor (IDI).

As an insect development inhibitor, PROGRAM Flavor Tabs do not kill adult fleas, but effectively and safely control flea populations on your cat by breaking the flea's life cycle at the egg stage.

Indications

PROGRAM Flavor Tabs are indicated for use in cats and kittens, four weeks of age and older, for the control of flea populations.

Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. You may also need to use a product that kills adult fleas.

PROGRAM Flavor Tabs may be used along with CAPSTAR (nitenpyram) Tablets to provide a Flea Management System that kills adult fleas and prevents flea eggs from hatching. Please see the Supplemental Package Insert provided with this product for information about using the two products together.

Without concurrent use of an adulticide, adequate flea control may not be achieved in dogs that have repeated exposure to flea infested animals or environments.

Precautions

PROGRAM Flavor Tabs have no effect on adult fleas, but act to immediately break the flea life cycle by preventing eggs from developing into adults. However, pre-existing immature fleas in the cat's environment may continue to develop and emerge as adults after treatment with PROGRAM Flavor Tabs has begun. Based on results of clinical studies, this emergence generally occurs during the first 30-60 days. Therefore, if your pet already has a flea infestation before starting PROGRAM Flavor Tabs, noticeable results may not be observed until several weeks after dosing. In cooler climates, immature fleas may take longer to complete the life cycle and emerge as adults.

To speed control, products that kill adult fleas, like Capstar may be used temporarily with PROGRAM Flavor Tabs, depending on the severity of the infestation. Your veterinarian can recommend the most effective treatment plan for your pet.

To ensure that your pet gets the greatest benefit from PROGRAM Flavor Tabs, you must administer the dose once a month in conjunction with a normal meal. If you miss the 30-day interval, administer PROGRAM Flavor Tabs immediately and resume your monthly dosing schedule. It is important to treat all cats in the household. Fleas can reproduce on untreated pets and allow infestations to persist. All dogs in the household should be treated with an approved product like lufenuron.

The active ingredient in PROGRAM Flavor Tabs is excreted in high concentrations in the milk, however, no resulting adverse effects have been recognized.

Flea Infestations on Cats

Although other flea species may be found on cats, the cat flea (*Ctenocephalides felis*) is the predominant flea associated with infestations on cats in the United States. In addition to the common nuisance irritations associated with infestations, fleas can be responsible for medical problems in your pet such as mild dermatitis, a skin reaction to flea bites. Fleas also transmit other parasites including tapeworms. Controlling flea infestations is important to your cat's health while also reducing the major and minor annoyances associated with these parasites.

The following diagram illustrates the flea's life cycle and where PROGRAM Flavor Tabs acts to break this cycle:

Life Cycle of the Flea



Fleas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your cat and subsequently lay eggs which drop off your cat's coat. Within days, larvae hatch from the eggs and live undetected in your cat's surroundings such as the carpet, bedding, and other protected areas. Flea larvae spin a cocoon, and when appropriately stimulated, a young adult flea emerges and jumps onto your cat to continue the life cycle. After biting a PROGRAM Flavor Tabs treated cat, the female flea ingests lufenuron which is deposited in her eggs. Lufenuron prevents these eggs from hatching and developing into mature adults. This safe and convenient approach to flea control effectively breaks the flea's life cycle and controls flea populations.

Dosage

PROGRAM Flavor Tabs are given orally, once a month, at the recommended minimum dosage of 13.6 mg lufenuron per pound (30 mg/kg) of body weight.

Program + Capstar CAT Insert
05/13/03 12:39 PM
CONFIDENTIAL DRAFT

Recommended Dosage Schedule

Body Weight	Dose	Lufenuron Per Tablet
Up to 6 lbs.	One Tablet	90.0 mg
7 to 15 lbs.	One Tablet	204.9 mg

Cats over 15 lbs. are provided the appropriate combination of tablets.

***Please see supplemental insert in this package for concurrent dosing of PROGRAM Flavor Tabs and CAPSTAR Tablets.**

Once A Month

PROGRAM Flavor Tabs will safely and effectively control flea infestations only if administered on a monthly dosing schedule. To help you remember the monthly dosing, use the enclosed reminder stickers on the appropriate dates on your calendar.

Adverse Reactions

The following adverse reactions have been reported in cats after giving PROGRAM Flavor Tabs: vomiting, depression/lethargy, anorexia (loss of appetite), diarrhea, hyperactivity, dyspnea (labored breathing), pruritus (itchy skin), and skin eruptions (rash).

How Supplied

PROGRAM Flavor Tabs are available in two tablet sizes (see Dosage section), formulated according to the weight of the cat. Each tablet size is available in color-coded packages of 6 tablets each.

Storage Conditions

PROGRAM Flavor Tabs should be stored at room temperature between 59° and 86°F (15-30°C).

Questions? Comments?

Please call 1-800-332-2761

Visit our website at www.petwellness.com

Manufactured for: Novartis Animal Health US, Inc.
Greensboro, NC 27408, USA

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NAH/PRO-FT/P1/3
DRAFT 01/03

PROGRAM (Brown/ up to 10 lbs.) with Swoosh

LOT
EXP.

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES UP TO 10 lbs.

PROGRAM
(LUFENURON) Flavor Tabs

GIVE
WITH A
MEAL



Once-a-month Flavor Tabs for the prevention and control of flea populations in dogs.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

NADA 141013 Approved by the FDA • Product #30111
Net Content: 30 Tablets 45 mg Lufenuron each

NOVARTIS

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES UP TO 10 lbs.

Also available in additional package sizes for other weight ranges.

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES UP TO 10 lbs.

Also available in additional package sizes for other weight ranges.

PROGRAM
(LUFENURON) Flavor Tabs

Important directions for use

- To ensure complete absorption, always administer PROGRAM (lufenuron) Flavor Tabs to dogs immediately after or in conjunction with a normal meal.
- PROGRAM Flavor Tabs have no effect on adult fleas, but control flea populations by breaking the flea life cycle at the egg stage.
- To speed control, products that kill adult fleas, like CAPSTAR (nitenpyram) Tablets, may be used temporarily with PROGRAM Flavor Tabs, depending on the severity of the infestation.
- Treatment should begin early in the flea season and should continue until the end of the flea season. If there is a risk of exposure to fleas year round, then treatment should continue the entire year without interruption.
- It is important to treat all dogs in the household. Cats in the same household should be treated with approved products like lufenuron.
- PROGRAM Flavor Tabs must be administered monthly, preferably on the same date each month.

For full product information, read package insert.

Storage Conditions: PROGRAM Flavor Tabs should be stored at room temperature between 59° and 86°F (15° - 30°C).

If you have any questions concerning the use of this product, contact your veterinarian, who is your pet's healthcare expert.

For technical assistance
call 1-800-332-2761.

www.petwellness.com

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NOVARTIS

LOT
EXP.

PROGRAM
Flavor Tabs

FOR DOGS & PUPPIES 11 TO 20 lbs. / FOR CATS & KITTENS UP TO 6 lbs.

PROGRAM
(LUFENURON) Flavor Tabs

GIVE
WITH A
MEAL



Once-a-month Flavor Tabs for the prevention and control of flea populations in dogs and for the control of flea populations in cats.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

NADA #141-035 • Approved by the FDA • Product # 301
Net Content: 30 mg Lufenuron Tablets

NOVARTIS

PROGRAM
Flavor Tabs

FOR DOGS AND PUPPIES 11 TO 20 lbs.
AND FOR CATS AND KITTENS UP TO 6 lbs.
Also available in additional package
sizes for other weight ranges.

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES 11 TO 20 lbs.
AND FOR CATS AND KITTENS UP TO 6 lbs.
Also available in additional package
sizes for other weight ranges.

PROGRAM (Green/11-20 lbs./cats to 6 lbs.)

PROGRAM
(LUFENURON) Flavor Tabs

Important directions for use

- To ensure complete absorption, always administer PROGRAM® (lufenuron) Flavor Tabs® to dogs and cats immediately after or in conjunction with a normal meal.
- PROGRAM Flavor Tabs have no effect on adult fleas, but control flea populations by blocking the flea life cycle at the egg stage.
- To speed control, products that kill fleas like CAPSTAR® (nitenpyram) Tablets may be used temporarily with PROGRAM Flavor Tabs depending on the severity of the infestation.
- Treatment should begin early in the flea season and should continue until the end of the flea season. If there is a risk of exposure to fleas year round, then treatment should continue the entire year without interruption.
- It is important to treat all dogs and cats in the household.
- PROGRAM Flavor Tabs must be administered monthly, preferably on the same date each month.

For full product information, read package insert.

Storage Conditions: PROGRAM Flavor Tabs should be stored at room temperature between 59° and 86°F (15° - 30°C).

If you have any questions concerning the use of this product, contact your veterinarian, who is your pet's healthcare expert.

NOVARTIS

PROGRAM (yellow/21 to 45 lbs. & cats 7 to 15 lbs.)

EXP.
LOT
PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS & PUPPIES 21 TO 45 lbs. / FOR CATS & KITTENS 7 TO 15 lbs.

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES 21 TO 45 lbs.
AND FOR CATS AND KITTENS 7 TO 15 lbs.
Also available in additional package
sizes for other weight ranges.

PROGRAM
(LUFENURON) Flavor Tabs

GIVE
WITH A
MEAL



Once-a-month Flavor Tabs for the prevention and
control of flea populations in dogs and for the
control of flea populations in cats.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

NADA #141-035 • Approved by the FDA • Product #30131
Net Contents: 6 Tablets 204.9 mg Lufenuron each

NOVARTIS

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES 21 TO 45 lbs.
AND FOR CATS AND KITTENS 7 TO 15 lbs.
Also available in additional package
sizes for other weight ranges.

PROGRAM
(LUFENURON) Flavor Tabs

Important directions for use

- To ensure complete absorption, always administer PROGRAM® (lufenuron) Flavor Tabs® to dogs and cats immediately after or in conjunction with a normal meal.
- PROGRAM Flavor Tabs have no effect on adult fleas, but control flea populations by breaking the flea life cycle at the egg stage.
- To speed control, products that kill adult fleas, like CAPSTAR® (nitenpyram) Tablets, may be used temporarily with PROGRAM Flavor Tabs, depending on the severity of the infestation.
- Treatment should begin early in the flea season and should continue until the end of the flea season. If there is a risk of exposure to fleas year round, then treatment should continue the entire year without interruption.
- It is important to treat all dogs and cats in the household.
- PROGRAM Flavor Tabs must be administered monthly, preferably on the same date each month.

For full product information,
read package insert.

Storage Conditions: PROGRAM Flavor Tabs should be stored at room temperature between 59° and 86°F (15° - 30°C).

If you have any questions concerning the use of this product, contact your veterinarian, who is your pet's healthcare expert.

NOVARTIS

For technical assistance
call 1-800-332-2761.

www.petwellness.com

NAH/PRO-FT/204.9/UDC/4

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES 46 TO 90 lbs.
Also available in additional package
sizes for other weight ranges.

FOR DOGS AND PUPPIES 46 TO 90 lbs.

PROGRAM
(LUFENURON) Flavor Tabs

GIVE
WITH A
MEAL



Once-a-month Flavor Tabs for the prevention and
control of flea populations in dogs.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

NADA #141-035 • Approved by the FDA • Product #30141
Net Contents: 6 Tablets 409.8 mg Lufenuron each

 **NOVARTIS**

PROGRAM
(LUFENURON) Flavor Tabs
LOT
EXP.

PROGRAM
(LUFENURON) Flavor Tabs

FOR DOGS AND PUPPIES 46 TO 90 lbs.
Also available in additional package
sizes for other weight ranges.

PROGRAM (White/46 to 90 lbs.)

PROGRAM
(LUFENURON) Flavor Tabs

Important directions for use

- To ensure complete absorption, always administer PROGRAM (lufenuron) Flavor Tabs to dogs immediately after or in conjunction with a normal meal.
- PROGRAM Flavor Tabs have no effect on adult fleas, but control flea populations by breaking the flea life cycle at the egg stage.
- To speed control, products that kill adult fleas, like CAPSTAR (nitenpyram) Tablets, may be used temporarily with PROGRAM Flavor Tabs, depending on the severity of the infestation.
- Treatment should begin early in the flea season and should continue until the end of the flea season. If there is a risk of exposure to fleas year round, then treatment should continue the entire year without interruption.
- It is important to treat all dogs in the household. Cats in the same household should be treated with approved products like lufenuron.
- PROGRAM Flavor Tabs must be administered monthly, preferably on the same date each month.

For full product information,
read package insert.

Storage Conditions: PROGRAM Flavor Tabs
should be stored at room temperature between 59°
and 86°F (15° - 30°C).

If you have any questions concerning the use of this
product, contact your veterinarian, who is your pet's
healthcare expert.

For technical assistance
call 1 800-332-2761.

www.petwellness.com

NAH/PRO-FT-CLW/409.8/UDC/1
709322

 **NOVARTIS**